DISTRICT OF MASSACHUSETTS

DARLENE BERNARD,

Plaintiff,

v.

No. 07 CA 40254 FDS

MERCK & CO., INC., and PFIZER, INC.

Defendants.

ANSWER TO COMPLAINT AND JURY DEMAND

Defendant Merck & Co., Inc. ("Merck") states the following, in answer to the numbered allegations contained in the Complaint of Darlene Bernard:

RESPONSE TO "THE PARTIES"

- 1. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the first sentence of Paragraph 1 of the Complaint. Merck denies each and every allegation set forth in the second sentence of Paragraph 1 of the Complaint except admits that Plaintiff purports to bring the referenced action but denies that there is any legal or factual basis for same.
- 2. Defendant Merck denies each and every allegation set forth in Paragraph 2 of the Complaint, except avers that Merck is a New Jersey corporation with its principal place of business in Whitehouse Station, New Jersey, and admits Merck manufactured, marketed and distributed Vioxx until it voluntarily withdrew Vioxx from the worldwide market on September 30, 2004, and that it is authorized to do business in Massachusetts.
- 3. The allegations contained in Paragraph 3 of the Complaint are not directed at Merck and therefore no responsive pleading is required.

- 4. Defendant Merck states that the allegations in Paragraph 4 of the Complaint are legal conclusions as to which no response is required. Should a response be deemed required, Merck denies each and every allegation set forth in Paragraph 4 of the Complaint, except admits that the parties are diverse and plaintiff purports to place an amount in controversy in excess of \$75,000, but denies there is any legal or factual basis for the relief sought. Merck further admits that it is authorized to conduct business in Massachusetts.
- 5. The allegations set forth in Paragraph 5 of the Complaint are legal conclusions as to which no response is required. Should a response be deemed required, Merck denies each and every allegation set forth in Paragraph 5 of the Complaint.

RESPONSE TO "INTRODUCTION"

- 6. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 6 of the Complaint. Merck denies each and every allegation directed at Merck in Paragraph 6 of the Complaint except admits that Vioxx is the brand name of the drug rofecoxib.
- 7. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 7 of the Complaint. Merck denies each and every allegation directed at Merck in Paragraph 7 of the Complaint except admits that is manufactured, marketed and distributed the prescription medicine Vioxx until Merck voluntary withdrew Vioxx from the worldwide market on September 30, 2004.

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- 8. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 8 of the Complaint. Merck denies each and every allegation directed at Merck in Paragraph 8 of the Complaint.
- 9. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 9 of the Complaint. Merck denies each and every allegation directed at Merck in Paragraph 9 of the Complaint except admits that the prescription medicine Vioxx is part of a class of drugs known as NSAIDS and that the prescription medicine Vioxx reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 ("COX-2").
- 10. Defendant Merck denies each and every allegation contained in Paragraph 10 of the Complaint, except admits that Merck sought, and, in May 1999, received FDA approval to manufacture and market Vioxx as safe and effective for certain indicated uses in a manner consistent with the information contained in the relevant FDA-approved prescribing information and respectfully refers the Court to the referenced prescribing information for its full text and for Vioxx's indicated uses.
- 11. Defendant Merck denies each and every allegation set forth in Paragraph 11 of the Complaint.
- 12. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in the first two sentences of Paragraph 12 of the Complaint. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the third sentence of Paragraph 12. Merck denies each and every allegation set forth in the fourth sentence of Paragraph 12.

- 13. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 13 of the Complaint. Merck denies each and every allegation directed at Merck in Paragraph 13 of the Complaint.
- 14. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 14 of the Complaint. Merck denies each and every allegation directed at Merck in Paragraph 14 of the Complaint.

RESPONSE TO "FACTUAL BACKGROUND"

RESPONSE TO "VIOXX's PRE-APPROVAL"

- 15. Defendant Merck denies each and every allegation contained in Paragraph 15 of the Complaint, except admits that in 1996 Merck proposed a study to investigate potential gastro-intestinal benefits of Vioxx over comparator drugs, but avers that the referenced study was cancelled in 1997.
- 16. Defendant Merck denies each and every allegation contained in the first sentence of Paragraph 16 of the Complaint except admits that Plaintiff purports to quote only a portion of the referenced memorandum and email and avers that the quoted language is taken out of context. Denies each and every allegation contained in the second sentence of paragraph 16 of the Complaint except admits that Plaintiff purports to quote a portion of a statement, but avers that said quoted language is taken out of context.
- 17. Defendant Merck denies each and every allegation contained in Paragraph 17 of the Complaint except admits that Plaintiff purports to quote portions of the referenced email but Merck avers that the quoted language is taken out of context.

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- 18. Defendant Merck denies each and every allegation contained in the first sentence of Paragraph 18 of the Complaint. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in the second sentence of Paragraph 18 of the Complaint.
- 19. Defendant Merck denies each and every allegation set forth in Paragraph 19 of the Complaint.

RESPONSE TO "VIOXX'S POST-APPROVAL"

- 20. Defendant Merck denies each and every allegation set forth in Paragraph 20 of the Complaint.
- 21. Defendant Merck denies each and every allegation set forth in Paragraph 21 of the Complaint except admits that the VIGOR study involving Vioxx exists and respectfully refers the Court to the referenced study for its actual conclusions and full text.
- 22. Defendant Merck denies each and every allegation set forth in Paragraph 22 of the Complaint except admits that Plaintiff purports to quote the referenced email, but Merck avers that said quote is taken out of context.
- 23. Defendant Merck denies each and every allegation contained in the first sentence of Paragraph 23 of the Complaint except admits that Merck has issued certain statements regarding Vioxx and respectfully refers the Court to the statement referenced by Plaintiff for its actual language and full text. Merck denies each and every allegation set forth in the remaining sentences of Paragraph 23 of the Complaint.
- 24. Defendant Merck denies each and every allegation contained in Paragraph 24 of the Complaint except admits that Merck issued a press release on April 28, 2000 entitled:

"Merck Confirms Favorable Cardiovascular Profile of Vioxx" and respectfully refers the Court to the referenced press release for its actual language and full text.

- 25. Defendant Merck denies each and every allegation contained in Paragraph 25 of the Complaint, except admits that the studies referenced in the first sentence of Paragraph 25 and the article referenced in the third sentence of Paragraph 25 exist, and respectfully refers the Court to said publications for their actual language and full text. Merck further admits that it is currently a member of the European League Against Rheumatisum ("EULAR") and that it has been a sponsor of EULAR since 1999.
- 26. Defendant Merck denies each and every allegation contained in Paragraph 26 of the Complaint except admits that 2000 worldwide Vioxx sales figures exceeded \$2 billion.
- 27. Defendant Merck denies each and every allegation contained in Paragraph 27 of the Complaint.
- 28. Defendant Merck denies each and every allegation contained in Paragraph 28 of the Complaint except admits that Plaintiff purports to characterize and quote from certain statements, but respectfully refers the Court to those statements for their actual language and full context.
- 29. Defendant Merck denies each and every allegation set forth in Paragraph 29 of the Complaint except admits that Plaintiffs purport to quote from Dr. Simon, but Merck avers that said quote is taken out of context.
- 30. Defendant Merck denies each and every allegation contained in Paragraph 30 of the Complaint except admits that the referenced publication exists and respectfully refers the Court to said publication for its actual language and full text.

- 31. Defendant Merck denies each and every allegation contained in Paragraph 31 of the Complaint and avers that Merck marketed the prescription medicine Vioxx in a manner consistent with its FDA-approved prescribing information. Merck further admits that in 2001 Vioxx achieved sales of \$2.6 billion and that Vioxx was prescribed to millions of patients.
- 32. Defendant Merck denies each and every allegation set forth in Paragraph 32 of the Complaint except admits that in April 2002 the FDA approved certain changes to the Vioxx prescribing information and respectfully refers the Court to the prescribing information for Vioxx for its actual language and full text.
- 33. Defendant Merck denies each and every allegation contained in Paragraph 33 of the Complaint except admits the existence of the journal, the article contained therein, and that plaintiff appears to have accurately quoted the document referenced in said paragraph, and respectfully refers the Court to the referenced document for its actual language and full text.
- 34. Defendant Merck denies each and every allegation set forth in the first two sentences of Paragraph 34 of the Complaint except admits that the referenced journals and articles contained therein exist, and that Plaintiff purports to quote from the same and respectfully refers the Court to said studies for their actual language and full context. Denies each and every allegation set forth in the third sentence of Paragraph 34 of the Complaint except admits that the referenced journal and article exist and respectfully refers the Court to said article for its actual language and full context.
- Defendant Merck denies each and every allegation set forth in Paragraph 35 of the 35. Complaint.
- 36. Defendant Merck denies each and every allegation set forth in Paragraph 36 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of DDMAC in

September 2001 and respectfully refers the Court to that letter for its actual language and full text.

- 37. Defendant Merck denies each and every allegation set forth in Paragraph 37 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.
- 38. Denies each and every allegation set forth in Paragraph 38 of the Complaint except admits that Merck marketed Vioxx in a manner consistent with the relevant FDAapproved prescribing information.
- 39. Defendant Merck denies each and every allegation set forth in Paragraph 39 of the Complaint except admits that Merck trains its professional representatives.
- 40. Defendant Merck denies each and every allegation set forth in Paragraph 40 of the Complaint except admits that in April 2002 the FDA approved certain changes to the Vioxx prescribing information and respectfully refers the Court to the prescribing information for Vioxx for its actual language and full text.
- 41. Defendant Merck denies each and every allegation contained in Paragraph 41 of the Complaint, except admits that the VALOR study was proposed as one of several options and that in a March 13, 2002 email the proposal was put on hold to explore other alternatives.
- 42. Defendant Merck denies each and every allegation contained in Paragraph 42 of the Complaint except admits the existence of the referenced article and respectfully refers the Court to said article for its actual language and full text. Merck denies each and every allegation set forth in the fourth sentence of Paragraph 42 of the Complaint and avers that the referenced action against Dr. Laporte and the Catalan Institute of Pharmacology was commenced by a

Merck subsidiary, MERCK SHARP & DOHME DE ESPANA, S.A. (MSD). Merck denies each and every allegation set forth in the fifth sentence of Paragraph 42 of the Complaint and respectfully refers the Court to the referenced decision for its actual language and full context.

- 43. Defendant Merck denies each and every allegation set forth in Paragraph 43 of the Complaint except admits that the referenced journal and article contained therein exist, and respectfully refers the Court to the referenced article for its actual language and full text. Merck further admits that Vioxx was prescribed to millions of patients by health care providers, and that Vioxx was registered, marketed and sold in approximately 80 countries outside the United States.
- 44. Denies each and every allegation contained in Paragraph 44 of the Complaint except admits that the presentation referenced in that paragraph exists, and respectfully refers the Court to the presentation for its actual language and full text.
- 45. Defendant Merck denies each and every allegation contained in Paragraph 45 of the Complaint except admits that in August 2004, Merck issued a press release regarding the conclusions of a study presented at the 20th International Conference of Pharmacoepideminology & Therapeutic Risk Management and respectfully refers the Court to that press release for its actual language and full text.
- 46. Defendant Merck denies each and every allegation contained in Paragraph 46 of the Complain except admits that on September 23, 2004, Merck was informed that the External Safety Monitoring Board ("ESMB") had recommended that the APPROVe study be stopped when preliminary results showed a small increased risk of confirmed cardiovascular events beginning after 18 months of continuous treatment with Vioxx.

47. Defendant Merck denies each and every allegation contained in Paragraph 47 of the Complaint except admits that on September 30, 2004, Merck announced the worldwide voluntary withdrawal of Vioxx. Merck further avers that it announced on September 30, 2004 that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking Vioxx compared with those taking placebo and that, given the availability of alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of Vioxx from the worldwide market best served the interests of patients. Merck further admits that Vioxx was prescribed to millions of patients by health care providers, and that Vioxx was registered, marketed and sold in approximately 80 countries outside the United States and that Vioxx worldwide sales figures exceeded \$2 billion in 2000, 2001, 2002, and 2003.

RESPONSE TO "CAUSES OF ACTIONS AGAINST MERCK"

- 48. Defendant Merck denies each and every allegation contained in Paragraph 48 of the Complaint.
- 49. Defendant Merck denies each and every allegation contained in Paragraph 49 of the Complaint.
- 50. Defendant Merck denies each and every allegation contained in Paragraph 50 of the Complaint.
- 51. Defendant Merck denies each and every allegation contained in Paragraph 51 of the Complaint.
- 52. Defendant Merck denies each and every allegation contained in Paragraph 52 of the Complaint.

53. Defendant Merck denies each and every allegation contained in Paragraph 53 of the Complaint except admits that Plaintiff seeks compensation for damages, but denies there is any legal or factual basis for such relief.

RESPONSE TO "COUNT I NEGLIGENCE AND GROSS NEGLIGENCE"

- 54. With respect to the allegations contained in Paragraph 54 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 55. Defendant Merck denies each and every allegation contained in Paragraph 55 of the Complaint.
- 56. The first sentence of Paragraph 56 contains legal conclusions to which no response is required. To the extent that a response is required, Merck denies that it violated any applicable law, duty or standard of care in connection with Vioxx. Merck denies each and every allegation contained in the second sentence of Paragraph 56, including subparts (a) through (q).
- 57. Defendant Merck denies each and every allegation contained in Paragraph 57 of the Complaint.

The "WHEREFORE" paragraph following Paragraph 57 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "COUNT II NEGLIGENCE - SALE OF PRODUCT"

- 58. With respect to the allegations contained in Paragraph 58 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 59. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 59 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx until Merck voluntarily withdrew Vioxx form the worldwide market on September 30, 2004.
- 60. Defendant Merck denies each and every allegation set forth in Paragraph 60 of the Complaint.
- 61. The allegations contained in Paragraph 61 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies that it violated any applicable law, duty or standard of care in connection with Vioxx.
- 62. The allegations contained in Paragraph 62 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies that it violated any applicable law, duty or standard of care in connection with Vioxx.
- 63. Defendant Merck denies each and every allegation contained in Paragraph 63 of the Complaint.
- Defendant Merck denies each and every allegation contained in Paragraph 64 of 64. the Complaint.
- Defendant Merck denies each and every allegation contained in Paragraph 65 of 65. the Complaint.

The "WHEREFORE" paragraph following Paragraph 65 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "COUNT III COMMON LAW FRAUD"

- 66. With respect to the allegations contained in Paragraph 66 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 67. The allegations contained in Paragraph 67 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.
- 68. The allegations contained in Paragraph 68 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies that it violated any applicable law, duty or standard of care in connection with Vioxx.
- 69. Defendant Merck denies each and every allegation contained in Paragraph 69 of the Complaint.
- 70. Defendant Merck denies each and every allegation contained in Paragraph 70 of the Complaint.
- 71. Defendant Merck denies each and every allegation contained in Paragraph 71 of the Complaint.

- 72. Defendant Merck denies each and every allegation contained in Paragraph 72 of the Complaint.
- 73. Defendant Merck denies each and every allegation contained in Paragraph 73 of the Complaint.
- 74. Defendant Merck denies each and every allegation contained in Paragraph 74 of the Complaint.

The "WHEREFORE" paragraph following Paragraph 74 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "COUNT IV BREACH OF EXPRESS AND IMPLIED WARRANTIES"

- 75. With respect to the allegations contained in Paragraph 75 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 76. Defendant Merck denies each and every allegation contained in Paragraph 76 of the Complaint.
- Defendant Merck denies each and every allegation contained in Paragraph 77 of 77. the Complaint.

- 78. The allegations contained in Paragraph 78 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.
- 79. Defendant Merck denies each and every allegation contained in Paragraph 79 of the Complaint.
- 80. Defendant Merck denies each and every allegation contained in Paragraph 80 of the Complaint.
- 81. Defendant Merck denies each and every allegation contained in Paragraph 81 of the Complaint.
- 82. Defendant Merck denies each and every allegation contained in Paragraph 82 of the Complaint.
- 83. Defendant Merck denies each and every allegation contained in Paragraph 83 of the Complaint.
- 84. Defendant Merck denies each and every allegation contained in Paragraph 84 of the Complaint, including subparagraphs (a) through (f).
- 85. Defendant Merck denies each and every allegation contained in Paragraph 85 of the Complaint.
- 86. Defendant Merck denies each and every allegation contained in Paragraph 86 of the Complaint.
- 87. Defendant Merck denies each and every allegation contained in Paragraph 87 of the Complaint.
- 88. Defendant Merck denies each and every allegation contained in Paragraph 88 of the Complaint.

- Defendant Merck denies each and every allegation contained in Paragraph 89 of 89. the Complaint including subparts (a) through (c).
- 90. Defendant Merck denies each and every allegation contained in Paragraph 90 of the Complaint.
- 91. Defendant Merck denies each and every allegation contained in Paragraph 91 of the Complaint.

The "WHEREFORE" paragraph following Paragraph 91 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "COUNT V NEGLIGENT MISREPRESENTATION"

- 92. With respect to the allegations contained in Paragraph 92 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 93. The allegations contained in Paragraph 93 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies that it violated any applicable law, duty or standard of care in connection with Vioxx.
- 94. Defendant Merck denies each and every allegation contained in Paragraph 94 of the Complaint.

- 95. Defendant Merck denies each and every allegation contained in Paragraph 95 of the Complaint.
- 96. Defendant Merck denies each and every allegation contained in Paragraph 96 of the Complaint.
- 97. Defendant Merck denies each and every allegation contained in Paragraph 97 of the Complaint.
- 98. Defendant Merck denies each and every allegation contained in Paragraph 98 of the Complaint.
- 99. Defendant Merck denies each and every allegation contained in Paragraph 99 of the Complaint.
- 100. Defendant Merck denies each and every allegation contained in Paragraph 100 of the Complaint.

The "WHEREFORE" paragraph following Paragraph 100 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "COUNT VI FRAUDULENT MISREPRESENTATION"

101. With respect to the allegations contained in Paragraph 101 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.

- 102. The allegations contained in Paragraph 102 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies that it violated any applicable law, duty or standard of care in connection with Vioxx.
- 103. Defendant Merck denies each and every allegation contained in Paragraph 103 of the Complaint.
- 104. Defendant Merck denies each and every allegation contained in Paragraph 104 of the Complaint.
- 105. Defendant Merck denies each and every allegation contained in Paragraph 105 of the Complaint.
- 106. Defendant Merck denies each and every allegation contained in Paragraph 106 of the Complaint.
- 107. Defendant Merck denies each and every allegation contained in Paragraph 107 of the Complaint.
- 108. Defendant Merck denies each and every allegation contained in Paragraph 108 of the Complaint.

The "WHEREFORE" paragraph following Paragraph 108 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

CAUSES OF ACTION AGAINST PFIZER

RESPONSE TO "COUNT VII NEGLIGENCE"

- 109. With respect to the allegations contained in Paragraph 109 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 110. The allegations contained in Paragraph 110 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 111. The allegations contained in Paragraph 111 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- The allegations contained in Paragraph 112 of the Complaint are not directed at 112. Merck and therefore no responsive pleading is required.
- 113. The allegations contained in Paragraph 113 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 114. The allegations contained in Paragraph 114 of the Complaint are not directed at Merck and therefore no responsive pleading is required..
- 115. The allegations contained in Paragraph 115 of the Complaint are not directed at Merck and therefore no responsive pleading is required.

The "WHEREFORE" paragraph following Paragraph 115 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "COUNT VII BREACH OF EXPRESS WARRANTIES"

- 116. With respect to the allegations contained in Paragraph 116 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 117. The allegations contained in Paragraph 117 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 118. The allegations contained in Paragraph 118 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 119. The allegations contained in Paragraph 119 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 120. The allegations contained in Paragraph 120 of the Complaint are not directed at Merck and therefore no responsive pleading is required.

The "WHEREFORE" paragraph following Paragraph 120 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "COUNT IX BREACH OF IMPLIED WARRANTIES OF MERCHANTIBILITY AND FITNESS FOR A PARTICULAR PURPOSE"

With respect to the allegations contained in Paragraph 121 of the Complaint, 121. Merck repeats and re-alleges each and every admission, denial, averment, and statement

contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.

- 122. The allegations contained in Paragraph 122 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 123. The allegations contained in Paragraph 123 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 124. The allegations contained in Paragraph 124 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 125. The allegations contained in Paragraph 125 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 126. The allegations contained in Paragraph 126 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 127. The allegations contained in Paragraph 127 of the Complaint are not directed at Merck and therefore no responsive pleading is required.

The "WHEREFORE" paragraph following Paragraph 127 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "COUNT X NEGLIGENT MISREPRESENTATION"

128. With respect to the allegations contained in Paragraph 128 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.

- 129. The allegations contained in Paragraph 129 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 130. The allegations contained in Paragraph 130 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 131. The allegations contained in Paragraph 131 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 132. The allegations contained in Paragraph 132 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 133. The allegations contained in Paragraph 133 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 134. The allegations contained in Paragraph 134 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 135. The allegations contained in Paragraph 135 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 136. The allegations contained in Paragraph 136 of the Complaint are not directed at Merck and therefore no responsive pleading is required.

The "WHEREFORE" paragraph following Paragraph 136 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "COUNT XI FRAUDULENT MISREPRESENTATION"

- 137. With respect to the allegations contained in Paragraph 137 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in the preceding paragraphs of this Answer with the same force and effect as though set forth here in full.
- 138. The allegations contained in Paragraph 138 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 139. The allegations contained in Paragraph 139 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 140. The allegations contained in Paragraph 140 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 141. The allegations contained in Paragraph 141 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- 142. The allegations contained in Paragraph 142 of the Complaint are not directed at Merck and therefore no responsive pleading is required.
- The allegations contained in Paragraph 143 of the Complaint are not directed at 143. Merck and therefore no responsive pleading is required.
- The allegations contained in Paragraph 144 of the Complaint are not directed at 144. Merck and therefore no responsive pleading is required.

The "WHEREFORE" paragraph following Paragraph 144 of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand compensatory damages, plus interests and costs, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "DISCOVERY RULE AND FRAUDULENT CONCEALMENT"

- 145. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 145 of the Complaint. The allegations directed at Merck in Paragraph 145 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in Paragraph 145 of the Complaint except admits that plaintiff purports to invoke the discovery rule to prevent her claim from being time barred but denies that there is any legal or factual basis for the same.
- 146. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 146 of the Complaint. The allegations directed at Merck in Paragraph 146 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in Paragraph 146 of the Complaint except admits that plaintiff purports to invoke the discovery rule to prevent her claim from being time barred but denies that there is any legal or factual basis for the same.
- 147. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 147 of the Complaint. The allegations directed at Merck in Paragraph 147 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in Paragraph 147 of the Complaint

except admits that plaintiff purports to invoke the discovery rule to prevent her claim from being time barred but denies that there is any legal or factual basis for the same.

- 148. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 148 of the Complaint. The allegations directed at Merck in Paragraph 148 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies that it violated any applicable law, duty or standard of care in connection with Vioxx except admits that plaintiff purports to invoke the discovery rule to prevent her claim from being time barred but denies that there is any legal or factual basis for the same.
- 149. Defendant Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in Paragraph 149 of the Complaint. The allegations directed at Merck in Paragraph 149 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in Paragraph 149 of the Complaint except admits that plaintiff purports to invoke the discovery rule to prevent her claim from being time barred but denies that there is any legal or factual basis for the same.

RESPONSE TO "PRAYERS FOR RELIEF"

The "Prayers for Relief" Paragraph is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in said paragraph, except admits that Plaintiff purports to demand judgment and certain forms of relief, but denies there is any legal or factual basis for awarding same.

RESPONSE TO "JURY DEMAND"

Merck admits that the Plaintiff demands a trial by jury.

JURY DEMAND

Merck hereby requests a trial by jury.

DEFENSES OF MERCK

FIRST DEFENSE OF MERCK

The Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE OF MERCK

Any product for which Merck was responsible at the time of the occurrence or injuries alleged by the Plaintiff was not defective and unreasonably dangerous in its design, manufacture, or marketing, and was at all times reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying the product or products at issue at the time of the occurrence or injuries alleged by the Plaintiff were legally adequate warnings and instructions.

THIRD DEFENSE OF MERCK

The occurrence and injuries alleged by the Plaintiff were caused or contributed to by the negligence, breaches of warranty, or defective products of third parties over whom Merck had no control and for whom Merck is not responsible.

FOURTH DEFENSE OF MERCK

If the Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons having no real or apparent authority to take said actions on behalf of Merck and over whom Merck had no

control and for whom Merck may not be held accountable.

FIFTH DEFENSE OF MERCK

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening causes which were the proximate and/or producing cause and/or the sole proximate and/or sole cause of the occurrence and injuries alleged by the Plaintiff. Moreover, the occurrence and injuries were caused by separate and independent events or agencies not reasonably foreseeable. Such separate and independent events or agencies destroy the causal connection, if any, between any breach of legal duty on the part of Merck and the occurrence and injuries alleged by the Plaintiff, and thereby become the immediate and/or sole cause, and/or sole proximate and/or sole producing cause of such occurrence and injuries, relieving Merck of liability to the Plaintiff or any other parties. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

SIXTH DEFENSE OF MERCK

If the Plaintiff sustained the injuries or losses alleged in the Complaint, upon information and belief, such injuries or losses were caused, in whole or in part, through the operation of nature or an act of God or other intervening cause or causes.

SEVENTH DEFENSE OF MERCK

If the Plaintiff sustained the injuries or losses alleged in the Complaint, the same were caused by an idiosyncratic reaction, without any negligence, defect, or failure on the part of Merck.

EIGHTH DEFENSE OF MERCK

The injuries and damages alleged in the Plaintiff's Complaint were the result of unavoidable circumstances that could not have been prevented by anyone, including Merck.

NINTH DEFENSE OF MERCK

If the Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Vioxx.

TENTH DEFENSE OF MERCK

The Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

ELEVENTH DEFENSE OF MERCK

The Plaintiff' claims are barred by the Plaintiff's contributory negligence and the contributory negligence of others.

TWELFTH DEFENSE OF MERCK

If the Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

THIRTEENTH DEFENSE OF MERCK

The Plaintiff's claims may be barred, in whole or in part, by the doctrine of laches.

FOURTEENTH DEFENSE OF MERCK

The benefits of the product or products at issue outweigh the risks, if any, that may be attendant to their use.

FIFTEENTH DEFENSE OF MERCK

If the Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions for which Merck is not responsible.

SIXTEENTH DEFENSE OF MERCK

The Plaintiff's claims are barred, in whole or in part, under Comment k of the Restatement (Second) of Torts § 402A.

SEVENTEENTH DEFENSE OF MERCK

The Plaintiff's claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

EIGHTEENTH DEFENSE OF MERCK

The Plaintiff's claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

NINETEENTH DEFENSE OF MERCK

The Plaintiff's claims are barred under Section 4 <u>et seq.</u> of the Restatement (Third), of Torts: Product Liability.

TWENTIETH DEFENSE OF MERCK

To the extent that Plaintiff asserts claims based upon alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of Vioxx, such claims are barred

under the learned intermediary doctrine because Merck has discharged its duty to warn in its warning to the prescribing physician.

TWENTY-FIRST DEFENSE OF MERCK

Merck has complied with all requirements of the Food and Drug Administration of the United States Department of Health and Human Services, and the product or products at issue were approved pursuant to the applicable statutes and regulations. Pursuant to such, the product or products at issue could only be used pursuant to the prescription of a licensed prescriber. The package insert for the product or products at issue was also approved by the Food and Drug Administration, and the marketing was conducted in conformity with the regulations of the Food and Drug Administration. Therefore, the Plaintiff's claims are preempted.

TWENTY-SECOND DEFENSE OF MERCK

The Plaintiff's claims may be time-barred, in whole or in part, under applicable statute(s) of limitations, statutes of repose, or are otherwise untimely.

TWENTY-THIRD DEFENSE OF MERCK

If the Plaintiff sustained the injuries or losses alleged in the Complaint, such injuries resulted, in whole or in part, from the negligence or fault of the Plaintiff and/or third parties, not from any negligence or breach of duty by Merck. Judgment may not enter for the Plaintiff if it is found that the Plaintiff was more negligent than Merck. If judgment is rendered in the Plaintiff's favor, the amount of such judgment must be reduced under the doctrine of comparative negligence.

TWENTY-FOURTH DEFENSE OF MERCK

To the extent the Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries or losses asserted in the Complaint, Merck's liability, if any, should

be reduced accordingly.

TWENTY-FIFTH DEFENSE OF MERCK

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

TWENTY-SIXTH DEFENSE OF MERCK

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

TWENTY-SEVENTH DEFENSE OF MERCK

Merck made no express or implied representations or warranties of any kind to the Plaintiff, nor did the Plaintiff rely on any representations or warranties made by Merck. To the extent the Plaintiff relied on any representations or warranties, such reliance was unjustified.

TWENTY-EIGHTH DEFENSE OF MERCK

Merck did not breach any duty of care to the Plaintiff.

TWENTY-NINTH DEFENSE OF MERCK

Each and every claim asserted or raised in the Complaint is barred by the doctrine of estoppel, waiver, or statutory and regulatory compliance.

THIRTIETH DEFENSE OF MERCK

The Plaintiff's claims may be barred, in whole or in part, from recovery because he has made statements or taken actions that preclude him from asserting claims or constitute a waiver of his claims.

THIRTY-FIRST DEFENSE OF MERCK

The Plaintiff has failed to join all necessary and indispensable parties.

THIRTY-SECOND DEFENSE OF MERCK

The Plaintiff's claims may be barred, in whole or in part, by Plaintiff's failure to mitigate his alleged damages.

THIRTY-THIRD DEFENSE OF MERCK

Merck did not violate any state or federal statute, regulation or ordinance to cause the Plaintiff's alleged injuries. Each and every claim asserted or raised in the Complaint is barred by the doctrine of statutory and regulatory compliance.

THIRTY-FOURTH DEFENSE OF MERCK

The Plaintiff's claims are barred, in whole or in part, due to a lack of notice.

THIRTY-FIFTH DEFENSE OF MERCK

To the extent that the Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

THIRTY-SIXTH DEFENSE OF MERCK

The Plaintiff's claims are barred, in whole or in part, because the Plaintiff lacks capacity and/or standing to bring such claims.

THIRTY-SEVENTH DEFENSE OF MERCK

To the extent the Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under Massachusetts law.

THIRTY-EIGHTH DEFENSE OF MERCK

The Plaintiff's state-law claims are barred, in whole or in part, because Vioxx was subject

to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

THIRTY-NINTH DEFENSE OF MERCK

The Complaint and the causes of action contained therein are barred, in whole or in part, by the United States and Massachusetts Constitutions, which prohibit the extraterritorial application of Massachusetts law.

FORTIETH DEFENSE OF MERCK

The Complaint and the causes of action contained therein are barred, in whole or in part, by the U.S. Constitution, article I, section VIII, clause 3 to the extent they seek to regulate Merck's practices outside of Massachusetts. That constitutional provision prohibits a State from regulating conduct that occurs wholly outside of its borders.

FORTY-FIRST DEFENSE OF MERCK

The Plaintiff's claims may be barred, in whole or in part, from recovery because of the res judicata effect of prior judgments.

FORTY-SECOND DEFENSE OF MERCK

The Plaintiff's claims of fraud are barred by reason of Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by MASS. R. CIV. P. 9 (b).

FORTY-THIRD DEFENSE OF MERCK

The Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and comparable provisions of the Massachusetts Declaration of Rights. To the extent the Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

FORTY-FOURTH DEFENSE OF MERCK

This case is more appropriately brought in a different venue.

FORTY-FIFTH DEFENSE OF MERCK

Venue in this case is improper.

FORTY-SIXTH DEFENSE OF MERCK

The Plaintiff's claims may be barred, in whole or in part, from recovery because, in this or other courts, they have brought actions and have received judgments on parts of some or all claims asserted herein.

FORTY-SEVENTH DEFENSE OF MERCK

The Plaintiff's claims may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

FORTY-EIGHTH DEFENSE OF MERCK

The Plaintiff's claims may be barred, in whole or in part, from recovery by release as to her claims.

FORTY-NINTH DEFENSE OF MERCK

The Plaintiff's claims may be barred, in whole or in part, from recovery due to spoliation of evidence.

FIFTIETH DEFENSE OF MERCK

The Plaintiff's claims may be barred, in whole or in part, by the governing state laws.

FIFTY-FIRST DEFENSE OF MERCK

Merck reserves its right to dismiss the Complaint and seek further relief for the Plaintiff's failure to provide it with due process of law.

FIFTY-SECOND DEFENSE OF MERCK

To the extent the Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity and/or because the alleged warranties were disclaimed.

FIFTY-THIRD DEFENSE OF MERCK

To the extent the Plaintiff seeks to recover only economic loss in tort, his claims are barred by the economic loss doctrine.

FIFTY-FOURTH DEFENSE OF MERCK

To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

FIFTY-FIFTH DEFENSE OF MERCK

Any warnings that Merck gave were transmitted to the prescribing physicians and/or health care providers, and under Massachusetts law Merck's only obligation is to warn the prescribing physician and/or health care providers and said obligation was fulfilled.

FIFTY-SIXTH DEFENSE OF MERCK

Defendant Pfizer, Inc. is improperly joined.

FIFTY-SEVENTH DEFENSE OF MERCK

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and

discovery in this action or that are included in the master answer to be filed in the Multidistrict

Litigation proceeding before Judge Fallon of the Eastern District of Louisiana. Merck hereby

reserves the right to amend its answer to assert any such defense. Merck incorporates any

applicable affirmative defense or other defense asserted by any other defendant in this action.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Defendant Merck & Co. respectfully requests that the Plaintiff take

nothing in this suit, that it recover its costs of court and expenses and such other relief to which it

may show itself justly entitled.

Respectfully submitted,

/s/ Catherine H. Wicker

James J. Dillon (BBO# 124660)

David E. Cole (BBO# 658705)

Catherine H. Wicker (BBO# 664326)

FOLEY HOAG LLP

155 Seaport Boulevard

Boston, MA 02110-2600

(617) 832-1000

Counsel for Merck & Co., Inc.

Dated: October 15, 2007

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CERTIFICATE OF SERVICE

I, Catherine H. Wicker, certify that this Answer to Complaint and Jury Claim filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on October 15, 2007.

_/s/ Catherine H. Wicker Catherine H. Wicker